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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/565,079

01/18/2006

Jun Keun Chang

CHANG216

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EXAMINER

KINGAN, TIMOTHY G

ART UNIT

PAPER NUMBER

1797

MAIL DATE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/565,079	<b>Applicant(s)</b> CHANG ET AL.	
	<b>Examiner</b> TIMOTHY G. KINGAN	<b>Art Unit</b> 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,5 and 7-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,5 and 7-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>06/18/2010</u> . | 6) <input type="checkbox"/> Other: ____.  |

## **DETAILED ACTION**

### ***Response to Arguments***

1. Applicant's arguments with respect to claim 1 have been considered but are moot in view of the new ground(s) of rejection. However, examiner notes (see below) that Qui teaches all elements of applicant's independent claim 1 with the exceptions of positive grid lines on the upper surface of the lower substrate and an upper substrate with a recess. As noted by applicant in the remarks of 04/16/2010, and with regard to the substrates defining the channel/chamber, Qui teaches fixing the upper and lower substrates via a tiered structure comprising a polymer film with adhesive on both sides, forming the elevation necessary for a counting chamber; Qui also teaches upper and lower substrates may be affixed with adhesive alone. While Qui does not teach the use of a first substrate with a recess on a surface, such element is known in the microfluidics art for defining a channel or chamber when fixed to a planar second substrate; further, devices so configured include those used for optical monitoring of events or particles in channels or chambers. One of ordinary skill in the art would recognize structural configurations of counting chambers comprising those defined by recesses and those defined by adhesive, with or without polymer film, as two species amongst a limited set capable of serving equivalent functions.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. **Claims 1, 2, 4, 5 and 7-9** are rejected under 35 U.S.C. 103(a) as being unpatentable over J. Qiu, U.S. Patent Application Publication 2004/0145805 (herein after Qiu; effective filing date 01/16/2003) in view of C.L. Hansen et al., U.S. Patent Application Publication 2003/0061687 (herein after Hansen), R. Nagle and C.B. Kennedy, U.S. Patent Application Publication 2002/0092973 (herein after Nagle) and B.J. Oberhardt, U.S. Patent Application Publication 2002/0028471 (herein after Oberhardt).

For Claims 1, 2 and 4, Qiu teaches a unitary device for counting cells comprising a top part, a connection part and a base part, a counting chamber with a grid of microscopic lines to define a counting area, the connection layer bonding the top part and the base part (abstract), further comprising two ports **22** for sample application in the top substrate and two ports **24** for air escape ([0016], [0035]; Fig. 1b) (upper substrate comprises a discharge hole), the top part made of a film or sheet of plastic or glass [0038] (transparent upper substrate) and the base part (lower substrate) providing optical clarity to permit focus under the field of view of an optical microscope [0048] (transparent lower substrate; area of the fill chamber is transparent). Qiu further teaches that the top part and base part (upper and lower substrates may be bound directly to

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one another by an adhesive to form an integrated body, the space formed thereby defining the counting chamber of a predetermined height ([0043] and [0042]).

Qui does not teach an upper substrate comprising a recess formed in its bottom surface. However, substrates with such recesses are known in the art for defining channels or chambers. Hansen teaches microfluidic devices comprising elastomeric layers formed on a machined mold to produce an upper substrate **24** with a recess in the bottom surface ([0123], Fig. 6, **21**), which, when sealed to a planar substrate **14**, forms a flow channel **30** ([128], Fig. 7B) (a unitary upper substrate comprising a recess in a bottom surface). That such manner of forming channels may be employed in optical detection is also known in the art. Nagle teaches a microfluidic device with integrated optical elements (title), the device comprising a planar substrate **110** with a groove or depression **114** (a recess on one surface) which, when fixed to a second planar substrate **102** forms a channel/chamber permitting optical detection ([0022], Figs. 2 and 4). It would have been obvious to one of ordinary skill in the art to use structural configurations of counting chambers comprising substrates with recesses fixed to planar substrates, according to the teachings of Hansen and Nagle, as an alternative to the use of a film stencil with adhesive or adhesive alone, amongst a small set of species for defining a counting chamber in the device of Qui, in order to provide the advantage associated with an elastomeric structure that may be peeled up, washed and re-used, according to the teaching of Hansen [0129].

While Qiu teaches that either the top substrate or the base part (upper or lower substrate) may contain precisely spaced lines in a grid pattern, which may be produced

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in substrate material by hot stamping or embossing [0053] to create positive grids (e.g., Fig. 3(d)) on either the top or bottom substrate (claims 2 and 4), including the upper surface of the bottom substrate (claim 5), the provisional application discloses formation of such grids only on the top substrate (60/440364, p. 2). However, grids formed on the lower substrate for counting cells in chambers are known in the art. Oberhardt teaches an apparatus and methods for cell analysis (title), such analysis including the counting of cells ([0041], [0190]) in a conduit comprising a capture zone positioned in an imaging field [0025], such capture zones having a textured surface that guides cells into discrete locations. Oberhardt further teaches the textured surface may take numerous forms to create a known x-y coordinate system including that of a saw-tooth grate [0190] (the teeth or ridges of which comprise a positive grid). Further, examiner notes that conventional hemacytometers place grid lines on the upper surface of a transparent lower substrate, that, when lines are formed by etching, result in a lattice pattern comprising a positive grid between etched grooves. It would have been obvious to one of ordinary skill in the art to use the positive grid system on the upper surface of the lower substrate, according to the teaching of Oberhardt and conventionally used in hemocytometers, in the device of Qiu, in order to provide for grid lines in close proximity to cells that may rest on the upper surface of the lower substrate, thereby improving imaging owing to the proximity of the planes of focus for cells and grid lines, as well as to provide a capture zone for improving the formation of an image owing to the reduction in movement associated with cells floating in medium.

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For Claim 5, Qiu teaches that the total thickness of the space (formed by a connecting layer or an adhesive) is chosen to be suitable for different sized cells and can range from 0.01 mm to 5 mm, preferably between 0.02 mm to 1 mm).

For Claim 7, Qiu, Hansen, Nagle and Oberhardt do not teach an indicative member on the upper substrate. It would have been obvious to one of ordinary skill in the art to place an indicative member on the upper substrate in order to facilitate coarse positioning of the counting chamber, and the lattice therein, the fine markings of which may otherwise be difficult to locate in a method of counting involving microscopy.

For Claim 8, Qiu teaches that the base part (lower substrate) may be fabricated from any transparent plastic sheet [0049].

For Claim 9, Qiu teaches that biological solutions suitable for use in cell counting microscopic particles include blood or cell culture [0005].

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIMOTHY G. KINGAN whose telephone number is (571)270-3720. The examiner can normally be reached on Monday-Friday, 8:30 A.M. to 5:00 P.M., E.S.T.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TGK

/Jill Warden/  
Supervisory Patent Examiner, Art Unit 1797